HFL-35

U.S. Food and Drug Administration

New York District
850 Third Avenue, Brooklyn, New York 11232

M1951N

Telephone: [718] 340-7000 [Ext 5532]

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Barry Geier, President
B & B Systems
12B Filmore Place
Freeport, NY 11520

May 15, 1998

Dear Mr. Geier:

During an April 21 to 28, 1998 inspection of your facility our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations for the manufacturing, processing, packing, or holding of drugs (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause containers of Liquid Oxygen U.S.P. filled by your firm and Oxygen U.S.P. gas distributed by your firm to be adulterated within the meaning of section 501(a)(2)(B) of the Food, Drug and Cosmetic Act (the Act).

At the conclusion of the inspection the investigator presented the enclosed Inspectional Observations (Form FDA 483) to you and discussed the findings. The following deviations pertaining to the processing of medical gases were found:

1. Failure to assure identity, purity, and strength of each incoming vessel of liquid oxygen. It was observed that you do not receive a valid Certificate of Analysis for each bulk vessel from your supplier. Therefore you must perform appropriate tests on each vessel prior to placing the incoming product into use for filling smaller vessels. The appropriate tests in this case are all of the tests in the U.S.P. for oxygen.

2. Failure to adequately maintain required production and control records.
   a. It was observed that records were prerecorded to show required prefill, fill, and postfill steps completed prior to the completion of the steps being recorded. This prerecorded record had blanks to fill in only for the lot number of the supplied oxygen, the date filled, and the serial numbers of the vessels which were filled. This prerecorded record was used for recording fill/test operations from 5/14/97 through 3/2/98.

b. Filling/testing records from 5/14/97 through 4/13/98 lack the filler's signature for each fill/test date.
c. It was observed that the liquid oxygen reconciliation records were not consistent with the filling/testing records. For example, for a total of [redacted] lots listed on the reconciliation record, the number of vessels filled for a given lot differed in a comparison of the reconciliation record with the filling/testing record for four of the lot numbers listed on both the fill/test record and the reconciliation record, and the lot number was missing from the filling/testing record in six instances. The filling/testing records had six instances found where a lot number was recorded as being processed but there was no corresponding reconciliation record for the lot.

3. Failure to adequately maintain required testing records.
   a. It was observed that records were prerecorded to show required testing steps completed prior to the completion of the tests being recorded. This prerecorded filling/testing record was found with already entered in information for tests showing a purity result of 100%. This prerecorded record had blanks to fill in only for the lot number of the supplied oxygen, the date filled, and the serial numbers of the vessels which were purportedly tested. This prerecorded record was used for recording fill/test operations from 5/14/97 through 3/2/98.
   b. Testing records for oxygen concentrations of patient's cryogenic vessels showed they failed to meet the U.S.P. requirements of not less than 99.0% on 3/9/98, 3/16/98, 3/23/98, 3/30/98 and 4/13/98 with no record of investigation of the failure found.
   c. A hammer test was recorded for patient's cryogenic vessels from 5/14/97 through 4/13/98, which test is appropriate for steel cylinders of compressed gas, not the insulated composite vessels of the liquid.

4. Failure to insure that each person engaged in the manufacture, processing of the oxygen has the education, training and experience to enable that person to perform the assigned functions.

5. Failure to maintain adequate records of label operations. There were no records to show the amount of labels issued, used, destroyed and the amount of labels currently in inventory.

6. Labeling was inadequate. Compressed gas cylinders that you distribute had labels that were torn, mutilated and lacked caution statements, indications, and directions for use. Your compressed gas labels were placed on cryogenic liquid vessels including supplier's GP-45 vessels and patient's home cryogenic vessels that you fill.

The above cited violations should not be regarded as all inclusive. It is your responsibility to ensure that all requirements of the Federal Food Drug and Cosmetic Act and all regulations promulgated thereunder, are being satisfied for all products subject to these requirements.

We request that you take prompt action to correct these deviations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the status of the specific steps you have taken or intend to take to correct the noted violations. You should report in writing those steps taken that may have already been witnessed by or explained to our investigator during the inspection. Include an explanation of each step being taken to prevent the recurrence of similar violations and a timetable for correction.

Your reply should be sent to the Food and Drug Administration, New York District Office, at the above address, Attention: William Friedrich, Compliance Officer.

Sincerely,

Brenda J. Holman

Brenda J. Holman
District Director
New York District